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| 10/584,983 | 04/12/2007 | Taehwan Kwak | CMT-0069 | 2395 |

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| EXAMINER |
|---|
| HOFFMAN, SUSAN COE |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1655 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/584,983 | KWAK ET AL. | |
| | Examiner | Art Unit | |
| | Susan Coe Hoffman | 1655 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,6-15,18-20 and 22-41* is/are pending in the application.

4a) Of the above claim(s) *11,13,18,20,22,24,26,27,30 and 32-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-10,12,14,15,19,23,25,28,29,31 and 35-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. The amendment filed January 29, 2009 has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.

2. Claims 16, 17, and 21 have been cancelled in this amendment.

3. Claims 1, 6-15, 18-20 and 22-41 are pending.

4. In the replies filed on April 24, 2008 and December 18, 2008 applicant elected cryptotanshinone and tanshinone IIA for species A, 1-beta-hydroxycryptotanshinone for species B and obesity for species C with traverse. The amendment filed January 29, 2009 amends claim 1 such that cryptotanshinone, tanshinone IIA and an additional compound selected from tanshinone I and 15,16-dihydrotanshinone I are required. Thus, the search for species A is extended to cover cryptotanshinone, tanshinone IIA and tanshinone I (see MPEP 803.02).

Applicant's additional arguments traversing the restriction requirement are noted but are not persuasive. The anticipatory references below show a lack of unity between the species.

5. Claims 11, 13, 18, 20, 22, 24, 26, 27, 30, 32-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

6. Claims 1, 6-10, 12, 14, 15, 19, 23, 25, 28, 29, 31, and 35-41 are examined on the merits in regards to the elected species as present in the claims.

### *Claim Objections*

7. Claim 19 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the

claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 19 depends on claim 1 which requires cryptotanshinone, tanshinone IIA, and at least one of tanshinone I and 15,16-dihydrotanshinone I. However, claim 19 only requires tanshinone I because the additional ingredient are claimed as "optional." The requirement for only one ingredient conflicts with claim 1 and improperly broadens the scope of the claim.

***Claim Rejections - 35 USC § 112***

8. Claims 35-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing obesity, does not reasonably provide enablement for preventing obesity for the reasons set forth in the previous Office action.

Applicant argues that this rejection has been overcome because claim 1 has been amended to delete the term "preventing." However, claim 35 is still drawn to a pharmaceutical formulation for preventing obesity. Thus, claims 35-39 are considered properly rejected based on a lack of enablement for the reasons set forth in the previous Office action.

Claims 7-9, 19, 23, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 7-9 are indefinite because they discuss the ratio of one component to the remaining component(s). The parentheses around the "s" in components indicates that there can be one or more remaining components. However, claim 1 requires three components; thus,

components would necessarily be plural because there are at least two remaining components. Therefore, the indication of a single remaining component is confusing.

10. As discussed above in paragraph 7, claim 19 conflicts with the scope of claim 1. Thus, the metes and bounds of claim 19 are indefinite because it is unclear exactly what ingredients are required in the claim.

11. Claims 23 and 25 are indefinite because they depend from cancelled claims 17 and 16, respectively. For the sake of examination, these claims are examined as if they depend from claim 1.

### *Claim Rejections - 35 USC § 102*

12. Claims 1, 7-10, 12, 19, 23, 25, 28, 29, 31, 35, 37, 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Sucher (US 2002/0077352).

This reference teaches a composition comprising tanshinones from Saliva miltiorrhiza (see abstract). The composition contains 3.24% tanshinone I, 7.35% cryptotanshinone and 6.72% tanshinone IIA (see paragraph 19). These percentages result in a composition that contains the ratios claimed by applicant and in a composition with cryptotanshinone as the most abundant ingredient. The composition is formulated with carriers into oral and injectable preparations such as tablets, capsules, solutions, emulsions, and powders (see page 5).

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference does not teach cryptotanshinone but rather a structurally distinct compound cryptotanshinone III. However, the notation of "cryptotanshinone III" in figure 1C is referring to the number of the structure in relation to the

other structures taught in the reference. This is seen is paragraph 19 which states that the compound is "cryptotanshinone (structure III)…". Thus, the reference teaches cryptotanshinone not cryptotanshinone III as alleged by the applicant. A search of REGISTRY demonstrates that there is no compound known as "cryptotanshinone III." The applicant argues that the structure shown in the reference for cryptotanshinone is distinct from the structure shown in the current specification. However, an artisan of ordinary skill in the art would understand that the structure of cryptotanshinone shown in the reference has errors which lead to the differences seen between the reference structure and the structure disclosed in the specification. The difference between the reference structure and the structure disclosed in the specification is the depiction of double bonds in the six-membered ring which is linked to the two methyl groups. These double bonds show a structure that is not chemically possible because it contains carbons that have more than four bonds. Thus, an artisan of ordinary skill would understand that the structure shown in the reference contains errors but this would not detract from the teaching in the reference that the composition contains cryptotanshinone.

13. Claims 1, 7, 14, 19, 23, 25, 28, 29, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Tezuka (Chem. Pharm. Bull. (1997), vol. 45, no. 8, pp. 1306-1311).

This reference teaches a S. miltiorrhiza extract that contains 0.010% cryptotanshinone, 0.0046% tanshinone I, and 0.13% tanshinone IIA (see Chart 2).

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference does not teach a combination of two or more of the compounds. However, the reference teaches that the cryptotanshinone, tanshinone I, and tanshinone IIA are all present in the methanolic extract from Salvia

miltiorrhiza (see page 1307, first column). Thus, the reference does teach a composition which contains a combination of cryptotanshinone, tanshinone I, and tanshinone IIA.

Applicant also argues that the claims are allowable over the reference due to unexpected synergistic results. However, as discussed in MPEP section 716.01(a) "unexpected results … must be considered by the examiner in determining the issue of obviousness of claims for patentability under 35 U.S.C. 103…". Unexpected results are not persuasive in overcoming a 102 rejection.

14. Claims 1, 19, 23, 25, 28, 29, 31, 35, 37 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Wei (US 6,541,046).

This reference teaches a composition for controlling body weight comprising an extract from S. miltiorrhiza which contains tanshinone I, tanshinone IIA and cryptotanshinone (see column 9, lines 1-4). The composition is formulated into powders, capsules, or tablets or is added to foods or beverages (see column 1, lines 22-65).

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference teaches using the S. miltiorrhiza extract to address the problems associated with the natural herbal extracts and does not teach that the extract is effective for weight loss. However, claim 1 of the reference specifically states a "composition for hindering weight gain comprising…red sage root [S. miltiorrhiza]...". Thus, the reference is considered to explicitly teach using S. miltiorrhiza to hinder weight gain.

In addition, even if the reference did not explicitly teach this use, the reference composition is structurally the same as the claimed composition. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and

the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

15. Claims 40 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu (US 4,906,470).

This reference teaches a method for making a S. miltiorrhiza extract. The reference teaches extracting the dried plant in water followed by filtration and vacuum drying (see Example 6).

***Claim Rejections - 35 USC § 103***

16. Claims 1, 7-10, 14, 15 and 35-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sucher (US 2002/0077352).

The teachings of this reference are discussed above. The reference does not specifically using the tanshinone I, cryptotanshinone and tanshinone IIA in the ratios claimed by applicant or using these ingredients in the percentages and dosages claimed in claims 36 and 38. However, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The reference specifically teaches that the dosage of each ingredient can be chosen by the individual physician in view of the patient's condition, age, body weight and response to the drug. In addition, the reference teaches adjusting the dosages to produce appropriate plasma levels of the ingredients (see paragraphs 50 and 59). Thus, the reference acknowledges that the

amount of each ingredient can be varied to best suit the individual undergoing treatment. Therefore, it would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference does not render the claimed invention obvious because the reference does not teach cryptotanshinone as claimed. However, as discussed above, the reference is considered to teach cryptotanshinone as claimed.

17. Claims 1, 6-10, 12, 14, 15, 19, 23, 25, 28, 29, 31, 35-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sairafianpour (J. Nat. Prod. (2001), vol. 63, pp, 1398-1403), Park (Bull. Korean Chem. (1999), vol. 20, no. 8, pp. 925-8) and Yuan (CN 1264580 - English translation provided).

Sairafianpour teaches the pharmaceutical effects of both cryptotanshinone and 1-beta-hydroxycryptotanshinone. The reference teaches that both of these compounds function against human carcinoma (see abstract). The reference also teaches that cryptotanshinone is from S. miltiorrhiza (see page 1398).

Park teaches using tanshinone I to inhibit cancer cells. The reference teaches that the tanshinone I is extract from S. miltiorrhiza (see abstract).

Yuan teaches using tanshinone IIA to treat human carcinomas (see English abstract).

These references show that it was well known in the art at the time of the invention to use the claimed ingredients in compositions that treat cancer. It is well known that it is prima facie

obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used in compositions to treat cancer, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions to treat cancer. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; In re Crockett 126 USPQ 186.

The references do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The references teach that each of the claimed ingredients is a pharmaceutically active ingredient. An artisan of ordinary skill would routinely modify the amount of pharmaceutically active ingredients based on the patient's age, weight, gender, and

condition. Therefore, an artisan would have been motivated to modify the amount of each ingredient in the combination in order to formulate a product that best achieves the desired results set forth in the references. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

The references also do not specifically teach formulating the ingredients into the pharmaceutical forms claimed. However, these are well known pharmaceutical forms that would have been obvious for one of ordinary skill in the art to employ. Thus, the use of these forms is considered to be an obvious modification of the references.

With the inclusion of Park, this is a new ground of rejection. However, applicant's arguments regarding the combination of Sairafianpour and Yuan have been considered in as much as they apply to this new ground of rejection. In response to applicant's argument that neither Sairafianpour nor Yuan teach using the claimed components to treat obesity, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The prior art taken together teach a composition that is structurally the same as the claimed composition. Thus, the intended use is not considered to patentably distinguish the claimed composition from the composition taught by the references.

Applicant argues that the combination of two or more of the claimed components is allowable over the prior art because the combination produces synergistic results. Applicant argues that page 14, lines 6-12 and figures 17-19 support this claim for synergistic results.

However, as stated in the last Office action, these results appear to be additive because the results for the combined ingredients do not appear to be significantly more than the results for the individual ingredients. Applicant has offered no specific arguments to support the assertion and the results are not additive but are synergistic. Applicant has not explained how the data show statistically significant proof of synergism (see MPEP section 716.02(b)). In addition, the applicant argues that "the experimental results of the present specification ascertain sufficiently the synergistic effect in the wide range of the ratios." However, again applicant has not provided any specific argument to support this assertion. At the broadest, the claims do not require any ratio of ingredients at all. Figure 18 does show three different ratios of tanshionone I to cryptotanshinone at 1:4, 1:1 or 4:1. These results do not appear to be synergistic but rather additive as discussed above. In addition, these ratios are not commensurate in scope with the broad ratios in at least claim 7. Thus, applicant's allegations of unexpected results are not persuasive.

18. Claims 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tashiro (US 5,589,182).

This reference teaches a method of making a S. miltiorrhiza extract. The extract is made by extracting the plant material with water, filtering the extract and concentrating the extract (see column 7, lines 50-60 and column 8, lines 7-10). The reference does not specifically teach using vacuum concentration. However, vacuum concentration is a well known means for performing concentration. An artisan of ordinary skill would reasonably expect that this well known type of concentration would be useful in carrying out the concentration step taught in the reference. This

reasonable expectation of success would motivate the artisan to modify the reference to include vacuum concentration.

19. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 9:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Coe Hoffman/
Primary Examiner, Art Unit 1655